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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,408	01/04/2002	David Wallach	WALLACH=17A	3196
1444	7590	11/19/2004	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			ANDRES, JANET L	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,408

Applicant(s)

WALLACH ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-36, 39-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34-36, 39 and 42-49 is/are allowed.
- 6) ☒ Claim(s) 40, 41 and 50-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 30 August 2004 is acknowledged. Claims 34-36 and 39-56 are pending and under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Maintained

2. The rejection of claims 40, 41, and 50-55 under 35 U.S.C. 112, first paragraph, as lacking written description is maintained for reasons of record in the previous office action and applied to new claim 56.

Applicant argues that the present claims are not directed to compounds, but rather to process steps. Applicant argues that no written description rejections have been applied to the methods of isolating and identifying the compounds. Applicant argues that methods of producing proteins are known and that once a protein is isolated and identified the method of producing more of it is in the possession of the inventor. Applicant additionally argues that the inventor would be in possession of all of the sequences encoding it. Applicant concludes that the inventor would be in possession of producing the product once it is found.

Applicant's arguments have been fully considered but have not been found to be persuasive. That one may be in possession of a method of screening, and of identifying compounds selected by the screen, does not indicate that one is in possession of that which might be identified by the screen. In order to make something, one must know what it is. Methods of producing proteins are known and, as Applicant states, once a protein is isolated and identified the method of producing more of it is in the possession of the inventor. However, until the protein is isolated neither it nor the method of producing more of it are in possession of the

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inventor. The inventor would be in possession of the product once it is found. However, the inventor is clearly not in possession of what has yet to be found and thus cannot produce more of it.

3. The rejection of claims 40, 41, and 50-55 under 35 U.S.C. 112, first paragraph, as lacking enablement commensurate in scope with the claims is maintained for reasons of record in the previous office action and applied to new claim 56.

Applicant argues that the steps of isolating and identifying the compounds have been found to be enabled. Applicant argues that it is a trivial matter to produce a protein once it is identified and undue experimentation is not required. Applicant argues that the claims are not claiming unidentified proteins. Applicant argues that the claims may be readily searched. Applicant argues that the Examiner has not provided any reason why the production of any identified protein would not be enabled.

Applicant's arguments have been fully considered but have not been found to be persuasive. A screening method is different from a method of making. One of skill in the art might well be able to screen compounds. However, the nature of the compounds that will be identified by this method is not known. One cannot make something that has not been described. As Applicant states, it is a trivial matter to produce a protein once it has been identified. However, it is not a trivial matter to produce a protein that has not been identified. While Applicant is not claiming unidentified proteins, Applicant is claiming the means for making them. The production of any identified protein would be enabled; however, one cannot produce what one has not identified.

No statement was made by the Examiner as to search difficulties.

CLAIMS 34-36, 39, AND 42-49 ARE ALLOWED. CLAIMS 40, 41, AND 50-56 ARE REJECTED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.
18 November 2004


JANE
PRIMA